



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0593]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Eye Tracking Experimental Studies to Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Eye Tracking Experimental Studies to Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Eye Tracking Experimental Studies to Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys--(OMB Control Number 0910-NEW)

I. Background

Eye tracking is a consumer research technique often used to determine where a person is looking while interacting with a visual display, such as a product package and elements of information on the package. The technique collects eye movement data, i.e., fixations and saccades (jumps of the eye), which may be superimposed on the display image to reveal: (1) Which parts of the display captured the viewer's attention, (2) the order and path in which visual elements were seen, and (3) the length of time they were viewed. These data provide detailed information on what individuals pay attention to on product packages, how long they spend looking at different package elements, and how visual attention may be related to their reaction to the images (Refs. 1 to 4, 7). Data from eye tracking studies can also help improve questionnaire design. Different respondents may pay differing degrees of attention to the elements of a survey question or response options. Eye tracking data can help to identify the need and strategies for improving the design (Refs. 5 and 6). Finally, eye tracking data can provide information on the decision strategies that individuals use under different levels of time pressure, which can help reveal the influence of time on busy individuals' food choices (Refs. 4 and 7).

As a public health agency, FDA helps consumers make informed dietary decisions by regulating nutrition information on food labels, among other activities. An understanding of how visual elements (e.g., labeling statements such as claims, disclosure statements, logos, and Nutrition Facts label) influence consumers' perceptions and choices of products can assist us in developing labeling information to help consumers make informed dietary decisions. In addition, we use self-administered questionnaires in online experimental studies to assess consumer reactions to nutrition information on food packages. An understanding of how respondents react to survey materials that are presented visually will enhance our ability in collecting better consumer data to help us fulfill our missions.

The proposed data collection will use eye tracking research to examine consumers' eye movements to achieve three goals: (1) To better understand consumer reaction to specific food labeling information, (2) to better understand survey respondent reaction to specific survey questions related to nutrition and health, and (3) to better understand how time pressure influences the priority and quality of decision making and survey response. In order to observe consumers' eye movement in different types of settings, we propose to conduct two separate studies, one in each of two different settings. Study 1 is a laboratory study that will ask participants to view on a computer screen mockups of food labels and perform tasks as well as answer other survey questions. Study 2 is an in-store study that will record eye movement data from grocery shoppers while they shop for preselected product categories. The studies will use two different survey instruments. Study participants will come from two separate convenience samples.

A. Study 1 (Laboratory Study)

Study 1 is a controlled randomized experiment. It has two objectives. The first objective is to collect data on how consumers view and process label information. The data will be used to test the hypothesis that one or more label and information characteristics will cause variations in viewing and processing. In this proposed study, we will focus specifically on the following characteristics: (1) Presence and type of nutrition symbols, together with presence of claims, on the Principal Display Panel (PDP) of a conventional food; (2) presence of a disclosure statement (21 CFR 101.13(h)(1)-(3)) on the PDP of a conventional food that makes a nutrient content claim; (3) format of the Nutrition Facts label on a conventional food product; (4) presence of a Dietary Supplement Health and Education Act disclaimer on the PDP of a dietary supplement product that makes a structure/function claim; (5) presence and length of a qualified health claim on the PDP of a dietary supplement product; and (6) type of product.

Label images will be created to allow the study to focus on consumer reaction to specific components of information on a food label. All images will be mockups resembling food labels that may be found in the marketplace but without any real or fictitious brand name.

The second objective of Study 1 is to examine how time pressure affects information processing. We will use the data to test the hypothesis that time pressure will cause variations in participant reactions (notice, attention, use, perception, and intention) to information. To test this hypothesis, the study will, at certain selected questions, expose participants to two randomly assigned time conditions, such as no time limit and 10 seconds per question.

The study will also include certain questions selected from previous online research we have sponsored in order to examine which part(s) of a question or which response options participants notice and pay attention to when they are asked to answer the question.

In the study, we plan to collect data from 200 participants using a 15-minute computer-assisted self-administered questionnaire and a 5-minute debriefing questionnaire. Forty interviews are planned for each of 5 locations across the contiguous 48 States. Participants will be recruited from residents at each location, and the study will aim to have a reasonable degree of diversity in participant gender, age, and education. On a computer screen, participants will first view a series of label images. Then participants will answer a set of questions related to their reactions to the label images they see on the computer screen. Each participant will be randomly assigned to an experimental condition that differs primarily in label components and time limit. To help understand the data, the study will also collect information on each participant's background, such as health status, label reading behavior, and dietary preferences.

B. Study 2 (In-Store Study)

In Study 2, we plan to collect observations of what information grocery shoppers notice and pay attention to while they do their shopping in the store. The study will gather eye movement data to provide an indepth understanding of subconscious and conscious factors that influence food purchases. Specifically, the study will explore the role that the Principal Display Panel and other label information and components play in purchase decisions. We will use the data to test the hypotheses that product familiarity or personal needs will cause variations in information seeking and that design elements (e.g., prominence, text vs. graphics) will cause variations in information seeking. To keep the study within a manageable scope, only shoppers who plan to shop for one or more of preselected product categories will be eligible to participate. Other than product categories, however, participants will not be restricted to which products they examine, what label information they view, or how much time they spend in completing any part of the study. To help understand the data, the study will also collect information on each

participant's background, such as health status and shopping practices. In Study 2 we plan to collect data from 60 participants who will each spend an average of 45 minutes in the study, including a practice session, the shopping trip, and a debriefing. The study will be conducted in two different locations. Participants will be recruited at storefronts.

Both the laboratory study (Study 1) and the in-store study (Study 2) are part of our continuing effort to enable consumers to make informed dietary choices. We will use the studies to assess consumer attention to and use of various pieces of information on food packages and the information's influence on product perceptions and choices. The assessment will provide us with background information to help identify and develop more effective labeling information and education in the future. In addition, we will use data from Study 1 to assess consumer behaviors when they are asked to respond to a sample of questions used in the Agency's consumer research. The assessment will help enhance our ability to conduct research that provides useful information. Wherever possible, we will also attempt to compare findings from the two studies to assess the degree to which results observed in the laboratory reflect actual behaviors in the market. For example, do laboratory and in-store participants pay attention to different labeling elements when they make a shopping choice? Results of the study will not be used to develop population estimates.

In the Federal Register of June 15, 2012 (77 FR 35983), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received three comments. One comment addressed matters that were outside the scope of the information collection provisions and will not be discussed here. We respond to the remaining comments in this document. For ease of reading, we preface each comment with a numbered "Comment;" and each response by a corresponding "Response." We have numbered each comment to help

distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, or importance, or the order in which it was received.

(Comment 1) One comment recommended that we examine the accuracy of the eye tracking methodology in identifying label reading patterns before considering applying the methodology more broadly.

(Response) FDA agrees that it is important to assess the degree of accuracy the methodology can provide and we have taken this into consideration.

(Comment 2) One comment questioned whether the use of eye tracking methodology is essential to the regulation of food labeling.

(Response) Part of our mission is to help the public get accurate and science-based information needed to use foods to maintain and improve health (Ref. 8). To help accomplish this mission, we state in our 2011-2015 Strategic Plan that we will strengthen social and behavioral sciences to help consumers make informed decisions about regulated products (Ref. 9). As part of the strategy, the plan identifies needs in knowing the audience, ensuring audience understanding of information, and evaluating effectiveness of communication about regulated products (Ref. 9). We will use the proposed studies to assess consumer attention to and use of various pieces of information on food packages and the information's influence on product perceptions and choices. These findings can extend and compliment findings from other consumer research FDA conducts and help us identify and develop more effective food labeling information and education in the future. Therefore, the use of eye tracking methodology is valuable to our mission in providing the public accurate and science-based information.

(Comment 3) One comment questioned the practical utility of the information to be collected in the proposed studies. The comment stated that Study 1 would not yield nationally representative results because it uses a convenience sample and suggests this limitation be noted in the supporting statement accompanying the Federal Register 30-day notice. The comment also questioned whether the sample size of Study 2 (60 participants) would be sufficient to yield detailed conclusions.

(Response) The 60-day notice stated that the studies would not be used to develop national estimates. We repeat this statement in the supporting statement. Though the sample size of Study 2 is constrained by the available resource, the study will provide preliminary yet useful insights into consumer viewing experiences with food shopping.

(Comment 4) A comment asserted that wearing eye tracking eyeglasses and a headset for biometric measurement in Study 2 would cause study subjects to behave differently from how they shop typically, thus weakening the reliability of the data. Instead, the comment suggests using a virtual store methodology in a computer-assisted central location test.

(Response) The comment did not provide evidence to support its concern or to illustrate the advantages of a virtual store methodology over an eye tracking methodology. Therefore, because we do not have a sufficient basis to conclude that the comment's suggested methodology would be better suited for our purposes than the eye tracking methodology described in the 60-day notice, we decline to change the methodology for Study 2.

(Comment 5) A comment questioned the use of the word "healthy" in certain questions because the word has a regulatory meaning and consumers may not understand the regulatory criteria for the claim "healthy." The comment suggested replacing "healthy" with "nutritious." The comment also expressed concern about questions that ask participants their inferences about

the relationships between a product and the risk of diabetes and obesity or overweight. The comment reasoned that these health conditions should not be asked about because there are no current authorized health claims permitted for these conditions.

(Response) We disagree with the comment. The studies are not to examine whether or how consumers understand labeling regulations. Rather, part of the purpose of the studies is to better understand how consumers infer from labeling the characteristics of food products. As stated in the comment, consumers may not understand regulatory criteria for claims, including "healthy," and there are no authorized health claims that link a food to diabetes or obesity. Yet consumers make product inferences and decisions based on their own experiences and knowledge, with or without any understanding about labeling regulations. Hence, for consumer research purposes, it is valid and meaningful to include these terms and product-risk relationships as a measure of consumer product inferences.

(Comment 6) A comment questioned the relevance of a series of Study 1 questions related to participants' inferences of what health conditions to which a product may be related. The comment explained that these questions are not consistent with established policy regarding health claims.

(Response) We understand and acknowledge this concern. Upon further consideration of the purposes of the study and the time length of the interview, we have revised the content of the study and removed the questions the comment discussed.

(Comment 7) A comment made several editorial suggestions and clarifications to the proposed questionnaires. For example, the comment suggested that "lesser amount of fat" in one Study 1 question be corrected grammatically, that "if you are allowed to eat xx g of carbohydrate as a snack" in another Study 1 question be revised to say "if you wish to eat a food with xx g of

carbohydrate as a snack." The comment also asked that Study 2 clarify that the participants can select multiple items in a product category and revise the wording in one question to reflect this. The comment further asked that Study 2 clarify that the interviewer will escort the participants to the store aisle for the target product category.

(Response) We have considered and incorporated the suggestions, when appropriate, in the revised questionnaires. For example, in Study 1 we did not make the suggested correction on "less amount of fat" or the suggested revision on carbohydrate. Instead, being mindful of the length of the study instrument, these questions were removed and replaced with other questions. At the same time, we have made the two clarifications in Study 2.

(Comment 8) A comment suggested that we make the label and package designs available for public review.

(Response) We have included the label and package designs in the supporting statement.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Laboratory pretest invitation	30	1	30	0.033 (2 minutes)	1
Laboratory pretest	15	1	15	1	15
Laboratory study invitation	500	1	500	0.033 (2 minutes)	17
Laboratory study	200	1	200	0.333 (20 minutes)	67
In-store study invitation	300	1	300	0.083 (5 minutes)	25
In-store study	60	1	60	0.75 (45 minutes)	45
Total					170

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m.,

Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Jones, G. and M. Richardson, "An Objective Examination of Consumer Perception of Nutrition Information Based on Healthiness Ratings and Eye Movements," Public Health Nutrition, vol. 10, pp. 238-244, 2007.
2. Bialkova, S. and H. C. M. van Trijp, "What Determines Consumer Attention to Nutrition Labels?" Food Quality and Preference, vol. 21, pp. 1042-1051, 2010.
3. van Herpen, E. and H. C. M. van Trijp, "Front-of-Pack Nutrition Labels, Their Effect on Attention and Choices When Consumers Have Varying Goals and Time Constraints," Appetite, vol. 57, pp. 148-160, 2011.
4. Fox, R. J., D. M. Krugman, J. E. Fletcher, and P. M. Fischer, "Adolescents' Attention to Beer and Cigarette Print Ads and Associated Product Warnings," Journal of Advertising, vol. 27, pp. 57-68, 1998.
5. Galesic, M., R. Tourangeau, M. P. Couper, and F. G. Conrad, "Eye-Tracking Data: New Insights on Response Order Effects and Other Cognitive Shortcuts in Survey Responding," Public Opinion Quarterly, vol. 72, pp. 892-913, 2008.
6. Graesser, A. C., Z. Cai, M. M. Louwerse, and F. Daniel, "Question Understanding Aid (QUAID): A Web Facility That Tests Question Comprehensibility," Public Opinion Quarterly, vol. 70, pp. 3-22, 2006.
7. Reutskaja, E., R. Nagel, C. F. Camerer, and A. Rangel, "Search Dynamics in Consumer Choice Under Time Pressure: An Eye-Tracking Study," American Economic Review, vol. 101, pp. 900-926, 2011.

8. FDA, "What We Do." Available at

<http://www.fda.gov/AboutFDA/WhatWeDo/default.htm>.

9. FDA, "Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions About Regulated Products," Section 8 in Strategic Plan for Regulatory Science. Available at

<http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm268150.htm>.

Dated: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-16001 Filed 07/02/2013 at 8:45 am; Publication Date: 07/03/2013]